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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/496,243	02/01/2000	Hideki Hyodoh	UTKO.002	5915

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EXAMINER

PHANIJPHAND, GWEN G

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 11/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## ***Office Action Summary***

Application No.	Applicant(s)	
09/496,243	HYODOH ET AL.	
Examiner	Art Unit	
Gwen Phanijphand	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 01 February 2000 .

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-70 is/are pending in the application.  
4a) Of the above claim(s) 37-66 is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 1-16, 18-27, 29-33, 35, 36, and 67-70 is/are rejected.  
7)  Claim(s) 17, 28 and 34 is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.  
Application Page \_\_\_\_\_

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 2/01/00 is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some \* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.  
4)  Interview Summary (PTO-413) Paper No(s).       .  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1 through 36 and 67 through 70, drawn to an implantable device with a plurality of wires, classified in class 606, subclass 213.
  - II. Claim 37, drawn to biodegradable filaments, classified in 606, subclass 194.
  - III. Claims 38-50, drawn to a method of forming an implantable device with a plurality of wires, classified in class 600, subclass 36.
  - IV. Claims 51-61, drawn to a method of creating a body suitable for implantation, classified in class 606, subclass 200.
  - V. Claims 62-66, drawn to a device for delivering a body, classified in class 606, subclass 194.

Because these inventions are and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Mark Garrett on 10/09/02 a provisional election was made without traverse to prosecute the invention of Group I claims 1-36, 67-70. Affirmation of this election must be made by applicant in replying to this Office action. Claims 37-66 are withdrawn from consideration.

***Drawings***

The drawings are objected to because Figures 51-53, which claims 25-28 read on, do not clearly show “both ends of at least one shape memory wire being located proximate one end of the body”.

***Claim Rejections – 35 U.S.C. 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 70 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 70 comprises “loop-defining locations”, but these locations are not clearly described in specification.

***Claim Rejections – 35 U.S.C. 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 2, 5, 7, 10, 11, 18, 20, 21, 24, 25, 27, and 67-70 are rejected under 102(e) as being anticipated by U.S. Patent No. 5,968,088 to Hansen et al.

Regarding claim 1, Hansen et al. disclose in Fig. 4 a plurality of shape memory wires (elements 10 and 11; col. 11; ll. 52-57), woven together to form a body for implantation. The wires cross each other to form a plurality of angles with one being obtuse ( $\alpha$ ), and the value of the obtuse angle increases by axially compressing the body. Hansen et al. disclose both ends of the shape memory wire (13) being located proximate one end of the body. When the body is radially compressed, the body has a larger diameter (col. 2, ll. 21-24) and angle  $\alpha$  inherently increases. Hansen et al. describe one wire, wherein the wire spirals in two different directions. Wire 10 spirals in one direction and after a twist (13) wire 10 becomes wire 11, which spirals in an opposite direction.

Regarding claims 2 and 21, Hansen et al. discloses the memory wire comprising nitinol (col. 11; l. 52).

Regarding claim 5, Hansen et al. disclose the wires each having a diameter size of about .16 mm (col. 12, line 4), which falls into the range of about 0.006 to about 0.012 inches.

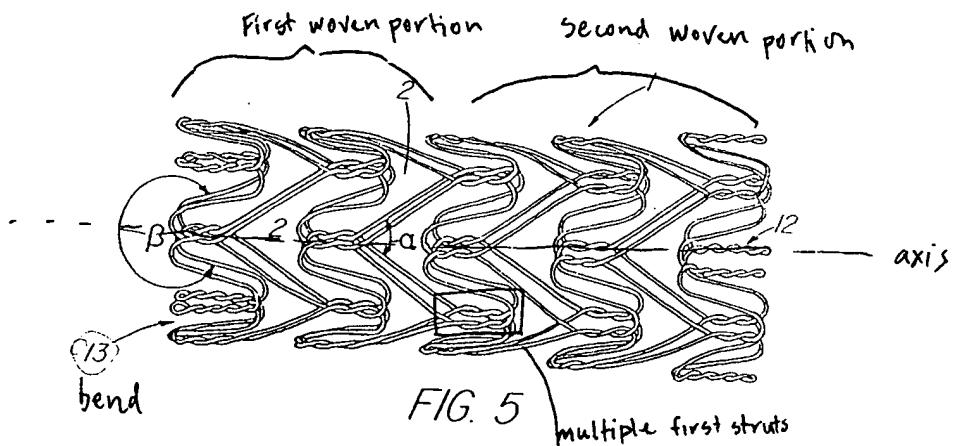
Regarding claim 7, Hansen et al. disclose the body having a tubular shape with a uniform diameter (col. 10, ll.25-26; l. 56).

Regarding claims 10 and 11, Hansen et al. disclose a woven body but do not disclose the process in which the body was made. Claims 10 and 11, however, are not given patentable weight since they are product-by-process type claims. A comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. *In re Fessman*, 489, F2d 742, 180 U.S.P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether it is known in the art or it is obvious, and not governed by whether the process by which it is made patentable.

In re Klug, 333 F2d 905, 142 U.S.P.Q. 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190, U.S. P.Q. 15, see footnote 3 (CCPA 1976).

Regarding claim 20, Hansen et al. disclose in Fig. 4 a device comprising at least  $n$  shape memory wires (elements 10 and 11; col. 11; ll. 52-57), wherein  $n$  being greater than one, and the  $n$  wires arranged such that the first portion comprises a woven portion and at least one strut (7).

Regarding claim 24, Hansen et al. disclose in Fig. 5 the body further comprising a second portion (the right side) adjacent the first portion (the left side). The second portion comprises a second woven portion, and has  $n + x$  shape memory wires (col. 11; ll. 52-57), wherein  $x$  is at least one.



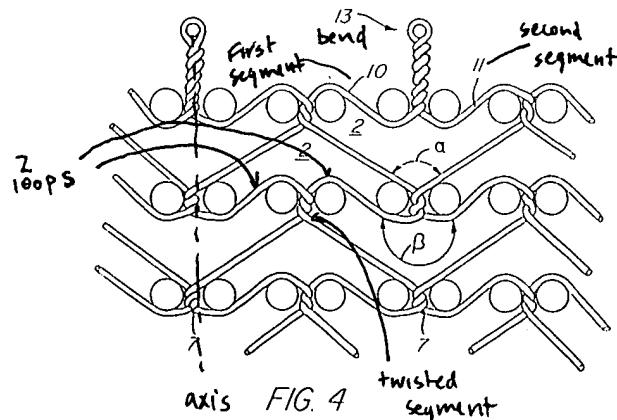
Regarding claim 25, Hansen et al. disclose the first portion (left side) comprising a first woven portion separated from a second woven (right side) portion by multiple first struts.

Regarding claim 67, Hansen et al. disclose in Fig. 5 a plurality of shape memory wires woven together (elements 10 and 11; col. 11; ll. 52-57), a body having first and

second ends (left and right ends), and both ends of the shape memory wire located proximate (13) one end of the body. The wires cross each other to form a plurality of angles with at least one angle,  $\beta$ , being obtuse (col. 4, ll. 43-49). When the body is radially compressed, the body has a larger diameter (col. 2, ll. 21-24), and the angle  $\beta$  inherently increases.

Regarding claim 68, Hansen et al. disclose in Fig. 5 a body having an axis, a first end (the left end), and a second end (the right end). The body in Fig. 4 comprises of shape memory wire (col. 11; ll. 52-57) having first (10) and second segments (11). The segments are separated by a bend (13) in the wire located proximate one end of the body. The first segment extends helically in a first direction around the axis toward the other end of the body, and the second segment extends helically in a second direction around the axis toward the other end of the body (col. 8, ll. 34-37). In Fig. 5, the first and second segments cross each other in a plurality of locations.

Regarding claim 69, Hansen et al. disclose a body in Fig. 5 having first (left end) and second (right end) ends, wherein the body in Fig. 4 comprises a memory wire (col. 11; ll. 52-57) having first (10) and a second (11) segments. The segments are separated by a bend in the wire (13) located proximate one end of the body. In Fig. 5, the first and second segments are arranged to form loops and twisted segments (7), such that at least two contiguous loops are separated by another loop by a twisted segment (Fig. 2).



Regarding claim 70, Hansen et al. discloses in Fig. 5 a body comprising a shape memory wire (col. 11; ll. 52-57) having a first segment and a second segment. The segments are separated by a bend in the wire (13) located proximate one end of the body. In Fig. 5, the segments are positioned adjacent to each other in loop-defining locations and extend between the loop-defining locations in spaced relation to each other so as to form at least two loops, one having a compressed shape.

***Claim Rejections – 35 U.S.C. 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 3, 4, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,968,088 to Hansen et al in view of U.S. Patent No. 6,306,105 B1 to Rooney et al. Hansen et al disclose wires comprising of Nitinol, a well known shape memory alloy, but do not disclose FePt, FePd, FeNiCoTi, FeNiC, FeMnSi, or FeMnSiCrNi as other possible compositions of the wires. Rooney et al., however, disclose a wire formed from nitinol or other alloys such as FEMnSi and FePt. As with nitinol, these alloys are advantageous because they provide strength for a wire to be introduced in a predetermined position but also allow the wire to restore to its original state due to its elastic properties. It would have been obvious to one of ordinary skill in the art at the time of the invention to add the other alloys, FeMnSi and FePt, as other materials for composing the wires of Hansen et al. so that these wires can exhibit

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elasticity while maintaining strength. The strength prevents buckling, and the elasticity provides more control and mobility.

3. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,968,088 to Hansen et al. Hansen et al. disclose a plurality of wires but do not disclose specifically at least 6 shape memory wires. It is, however, well known to vary the number of wires to 6 or more, depending on the material and the size of the wires. Creating a device of 6 or more wires is advantageous for larger vessels and cavities. It would have been obvious and well known to one having ordinary skill in the art at the time of the invention to create a device comprising of at least 6 woven wires so that the device can be more effective in larger vessels or cavities.

4. Claims 8, 9, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,968,088 to Hansen et al. In col. 7, ll. 27-31, Hansen et al. disclose the sections having varied shapes and multiple struts composed of memory wire, which inherently bend, increasing the self-anchoring capability of the body. Hansen et al., however, do not disclose a tapered shape, an hourglass shape, or a first portion having a domed shape. In stents, occlusive devices, or filters, it is common to find hourglass, tapered and domed shapes. It would have been obvious to one having ordinary skill in the art at the time of the invention to include domed, hourglass, and tapered shapes since these are well-known, varied shapes for stents, occlusive devices, and filters. These varied shapes are advantageous for fitting into different parts of the body.

5. Claims 18, 19, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,968,088 to Hansen et al in view of U.S. Patent No. 6,440,161 B1 to Madrid et al. In col. 5, ll. 46-47, Hansen et al. disclose delivering a stent

using a catheter but do not describe the structure of the catheter. Madrid et al., however, disclose in Fig. 14 a catheter with a first tube (164), configured to accept a guidewire (166) and a second tube (128), configured to fit over the first tube with one end of the body being secured to the first tube. This configuration of a catheter is well-known. It would have been obvious to one having ordinary skill in the art at the time of the invention to include a catheter with two tubes and a guidewire for delivering a stent since this catheter design is common and well known.

6. Claims 12-16 and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,968,088 to Hansen et al in view of U.S. Patent No. 6,019,786 to Thompson. Hansen et al. disclose a stent body but do not disclose a graft material attached to the body. Thompson et al. disclose a stent with a graft body attached and the graft material comprising polyester (col. 7, line 63), Dacron (col. 7, line 62), polyurethane (col. 12, line 22), and PTFE (col. 12, line 61). It is well-known to attach grafts to stent bodies to aid in delivery and increase the biocompatibility of the stent material. It is also well-known to compose grafts from polyester, Dacron, polyurethane, and PTFE. It would have been obvious and well known to one having ordinary skill in the art at the time of the invention to attach a graft to a stent body and compose the graft from polyester, Dacron, polyurethane, and PTFE, which are advantageous and well-known materials due to their high structural strength and elastic moduli.

*Allowable Subject Matter*

7. Claims 17, 28, and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gwen Phanijphand whose telephone number is 703-305-4845. The examiner can normally be reached on Mon-Fri.

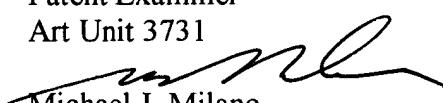
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

GP

November 14, 2002

Gwen Phanijphand  
Patent Examiner  
Art Unit 3731



Michael J. Milano  
Supervisory Patent Examiner  
Technology Center 3700